# sematid

# Semaglutide

#### Composition

Sematid 3: Each tablet contains Semaglutide INN 3 mg.
Sematid 7: Each tablet contains Semaglutide INN 7 mg.
Sematid 14: Each tablet contains Semaglutide INN 14 mg.

# Pharmacology

Semaglutide acts as a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. The GLP-1 receptor is the target for native GLP-1, an endogenous incretin hormone that potentiates glucose-dependent insulin secretion from the pancreatic beta cells. Unlike native GLP-1, Semaglutide has a half-life of approximately one week. This long plasma half-life is based on binding to albumin, which reduces renal clearance, and increased enzymatic stability towards the dipeptidyl peptidase (DPP-IV) enzyme.

Semaglutide action is mediated via a specific interaction with GLP-1 receptors, leading to an increase in cyclic adenosine monophosphate (cAMP). Semaglutide stimulates insulin secretion in a glucose-dependent manner. Simultaneously, Semaglutide lowers glucagon secretion, also in a glucose-dependent manner. Thus, when blood glucose is high, insulin secretion is stimulated and glucagon secretion is inhibited. The mechanism of blood glucose lowering also involves a delay in gastric emptying.

#### Indication

Sematid is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus:

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications;
- in combination with other medicinal products for the treatment of diabetes.

# **Dosage and Administration**

Route of administration: Oral.

**Recommended Starting Dose:** The starting dose of Sematid is 3 mg once daily. After 30 days, the dose should be increased to a maintenance dose of 7 mg once daily. If additional glycemic control is needed after at least 30 days on the 7 mg dose, the dose can be increased to a maintenance dose of 14 mg once daily.

OR AS DIRECTED BY THE PHYSICIAN.

# Contraindications

Sematid is contraindicated in patients who are hypersensitive to Sematid or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. Sematid is contraindicated in patients who have a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Sematid should not be used during pregnancy or breastfeeding.

# **Warning & Precaution**

- Should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Risk of Thyroid C-Cell Tumours
- patients should be advised to take precautions to avoid hypoglycemia while driving and using machines.
- Semaglutide causes an increase in heart rate. Caution should be observed in patients who have cardiac conditions that might be worsened by an increase in heart rate, such as tachyarrhythmias
- Patients treated with semaglutide in combination with an insulin secretagogue (e.g., sulfonylureas) or insulin may have an increased risk of hypoglycemia. The risk of hypoglycemia may be lowered by reducing the dose of the secretagogue or insulin when initiating treatment with Sematid.

#### **Side Effects**

**Common side effect:** Vomiting, upset stomach or indigestion inflamed stomach, reflux or heartburn or GERD, stomach pain, bloating of the stomach, constipation, change in the way food or drink tastes, tiredness, less appetite, gas (flatulence), increase of pancreatic enzymes (such as lipase and amylase).

Rare side effect: : serious allergic reactions (anaphylactic reactions). You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak.

# Use in Pregnancy & Lactation

**Pregnancy:** The extent of exposure in pregnancy during clinical trials was very limited and there are no adequate and well-controlled studies of Semaglutide in pregnant women. Therefore, Sematid should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, Sematid should be discontinued. Sematid should be discontinued at least 2 months before a planned pregnancy due to the long half-life of Semaglutide.

**Nursing Mothers:** Breastfeeding is not recommended during treatment with Sematid as a risk to the nursing infant cannot be excluded.

# Use in Children & Adolescents

The safety and efficacy of Sematid in children and adolescents below 18 years have not been studied.

#### **Drug Interactions**

**With medicine**: Semaglutide delays gastric emptying which may influence the absorption of other oral medications. Trials were conducted to study the potential effect of Semaglutide on the absorption of oral medicinal products taken with Semaglutide administered orally at steadystate exposure.

With food & others: Concomitant intake of food reduces the exposure of semaglutide.

#### Overdose

If Sematid is overdosed, than patient should talk to doctor. Patient may have side effects such as feeling sick (nausea).

# Storage

Store below 25°C temperature & dry place, protected from light. Keep out of reach of children. Sematid must be stored in the original blister packaging to protect from moisture and light. Take the tablet directly after removing from blister card.

# Packing

Sematid 3: Each box contains 1 x 10 tablets in Alu-Alu blister. Sematid 7: Each box contains 1 x 10 tablets in Alu-Alu blister. Sematid 14: Each box contains 1 x 10 tablets in Alu-Alu blister.

\* Further information is available on request.

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